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Design, Manufacture, and Selection of Ankle-Foot-Orthoses

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INTRODUCTION

Ankle-foot-orthoses (AFOs) are externally applied assistive devices that are prescribed to the patients with neuromuscular dysfunctions in order to improve abnormal lower limb motor functions. AFOs are mainly used to control the range of motion of the ankle joint, to compensate for the muscle weakness caused by different motor-neuron diseases, to improve the gait functions during post-operative stages and to optimize the efficiency of walking.

Different types of AFOs are used to treat different dysfunctions. Each type of AFOs has its characteristic function. However, AFOs with same function can have different designs that differ in material, geometry, additional mechanism and components which affect the comfort, cost of AFO and oxygen consumption of patients. Additionally, recent advances in different technology areas, such as additive manufacturing (AM), three dimensional (3D) scanning and CAD-CAM (computer aided design-computer aided manufacturing) have led to new designs and manufacturing methods for AFOs. The objective of this chapter is to provide a survey on design, manufacture and selection of AFOs.

BACKGROUND

First of all, it would be beneficial to describe orthosis and prosthesis concepts that are mostly confused with each other. Briefly, orthoses are braces to support dysfunction of a body part, while prostheses are artificial parts to replace a missing body part. Prostheses are devices for external and internal use. External prostheses, such as prosthetic legs or prosthetic breast form used after mastectomy (Lake, Ahmad, & Dobrashian, 2013), can be employed for cosmetic and also functional aims with the developments in prosthetic technology. On the other hand, internal prostheses, such as artificial knee joints (Guo, Hao, & Wan, 2016) and cataract lenses (Heys & Truscott, 2008) are devices which are surgically implanted within a body.

Orthoses are assistive devices that are used to align, protect and assist limbs or body parts besides supporting to treat deformities. Orthoses can be used for neurological conditions, injuries and congenital deformities. Orthoses are designed as standard or custom made forms from an individual mold in the shape of patient's foot. Orthoses can be divided into two classes, i.e. *i*) standard orthoses for general use and *ii*) custom made orthoses

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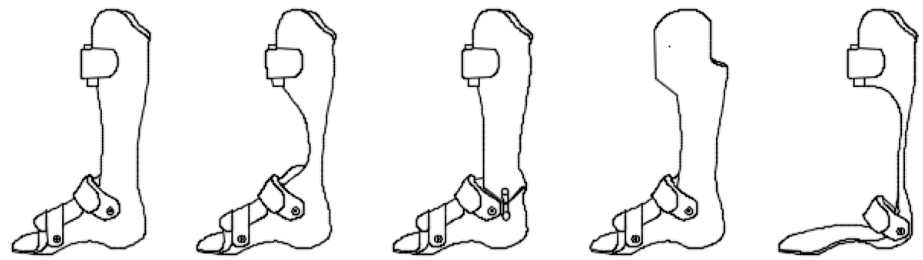
Figure 1. Typical examples of ankle foot orthoses



that are prescribed for more complex conditions. Orthoses are used for lower extremity (Moisan & Cantin, 2016), upper extremity (Belda-Lois et al., 2006), and spine (Hofmann et al., 2016). Lower extremity orthoses have a wide range of use that are designed for hip, knee and ankle joints' immobilizations. They reduce energy consumption and pain as assisting the gait and improving the posture. Development of lower extremity orthotic technologies and new materials lead to new designs and manufacturing methods, and also affect selection criteria of orthoses.

AFOs are braces encompassing the lower leg, ankle joint and foot of the patients. AFOs provide stability in the ankle joint and biomechanical control above and below of ankle. For example, a patient with crouch gait pathology (walking with flexed knees) can reduce knee flexion during stance phase by using an AFO. Because, AFO produces a moment around the ankle joint that prevents ankle dorsiflexion in stance phase which prevents excessive knee flexion by directing the ground reaction force in front of the knee joint center. They are manufactured using metal and plastic materials. However, plastic AFOs are more preferred than metal ones, because they are lighter and more cosmetic (Franceschini et al., 2001). Also it was reported that custom plastic AFOs decrease oxygen consumption in the patients. However, the patients, who want to use AFO, should have sufficient active hip flexion to propel their legs. And their quadriceps muscle strength should be greater than four or five grade according to manual muscle test (Hsu, Michael, & Fisk, 2008).

There are several different types of AFOs for different biomechanical aims (Figure 1). Solid ankle foot orthosis (SAFO) (Ridgewell, Rodda, Graham, & Sangeux, 2015) rigidly supports ankle and prevent any movement at the ankle. Dynamic ankle foot orthosis (DAFO) provides subtalar stabilization. Unlike solid AFO models, this device allows ankle to dorsiflex and partially limits the plantarflexion (Sherief, Gazya, & El Gafaar, 2015). Hinged ankle foot orthosis (HAFO) is also a type of dynamic AFO which let the dorsiflexion exists during gait. On the other hand, HAFO is commonly used to restrict three-dimensional ankle mobility and limit the motion of ankle joint within the sagittal plane (Leardini, Aquila, Caravaggi, Ferraresi, & Giannini, 2014). Ground reaction ankle foot orthosis (GRAFO) is used to reduce excessive knee flexion (Ries & Schwartz, 2015). This type of orthoses has a solid part below the knee (pre-tibial support) which doesn't allow the knee joint moving forward. Posterior leaf spring ankle foot orthosis (PLS AFO) is used to primarily for foot drop in order to control plantarflexion during heel strike and swing phases to improve the functional quality of locomotion (Leone, 1987). All these AFOs have different characteristics, since they are designed for specific goals. Different characteristics of AFOs meet specific needs which result from injuries and diseases, such as foot drop (Everaert et al., 2013), cerebral palsy (van Beeten, Hartman, & Houdijk, 2015), spina bifida (Duffy, 1997) and hemiplegia (Nolan, Savalia, Lequerica, & Elovic, 2009).

AFO, with physical therapy combination, is widely used to provide adequate proper heel contact at initial-contact, to prevent premature heel-rise and to increase stance phase stability during walking (Rethlefsen, Kay, Dennis, Forstein, & Tolo, 1999). Solid, articulated and leaf spring AFOs are widely used in clinics which, in literature, were reported improving gait velocity and gait dynamics (White, Jenkins, Neace, Tylkowski, & Walker, 2002), preventing excessive plantar flexion in stance, providing adequate dorsiflexion in initial-contact and swing phases (Lam, Leong, Li, Hu, & Lu, 2005; Romkes, Hell, & Brunner, 2006), and improving natural position of the foot in late swing for hemiplegic children (Van Gestel, Molenaers, Huenaerts, Seyler, & Desloovere, 2008). Solid AFOs are used to prevent excessive plantar and dorsiflexion of the ankle during walking to enhance the stability in stance, reduce the abnormal motion at ankle and foot. The simplest way of creating a hinge motion in AFO is to trim material away around the ankle, which makes the material more flexible at this point. This is so called posterior leaf spring AFO, which capable of limiting plantar flexion and allowing dorsiflexion as required. The amount of dorsiflexion is directly related with the amount of trimming from the back of the ankle (Morris, 2007). On the other hand, hinged AFO is only prescribed to prevent either plantar flexion or dorsiflexion of the ankle (Morris, 2007). It was revealed in literature that dynamic parameters of walking are significantly improved by using solid and articulated AFO, although, in terms of these gait parameters, there was no significant superiority of any of these AFOs on another (Radtka, Skinner, & Johanson, 2005; Radtka, Skinner, Dixon, & Johanson, 1997; Eddison & Chockalingam, 2013).

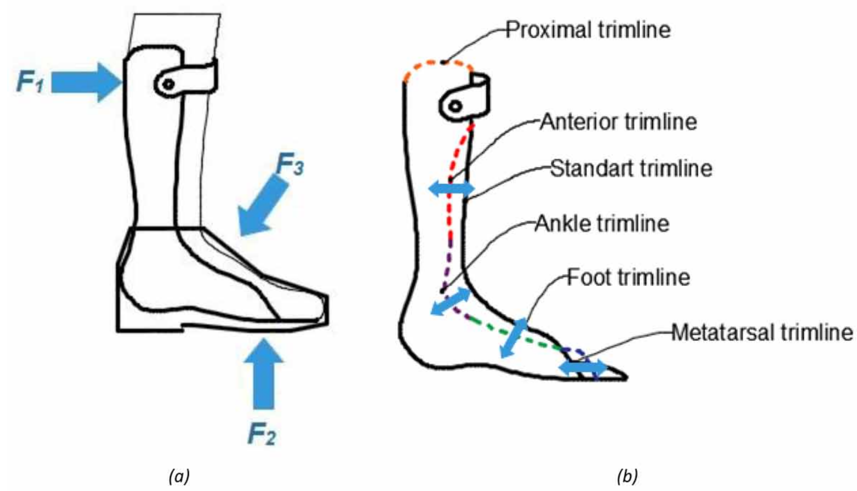
Sophisticated analysis tools (computerized gait analysis, force platform, electromyography etc.), video based gait analysis methods (Edinburg Visual Gait Scale) or functional assessment scales (Gross Motor Functional Measure, PEDI etc.) are utilized to evaluate the gait parameters (Bella, Rodrigues, Valenciano, Silva, & Souza, 2012; Dalvand, Dehghan, Feizi, Hosseini, & Amirsalari, 2013). These tools are valuable to compare the effects of the AFO for the patient and to tune the AFO in order to increase the influence on related gait parameters (gait velocity, step length, kinetics and kinematics).

DESIGN OF AFOS

AFO is designed to control the motion of the ankle joint, and to improve the gait function of patients with motor impairments. As shown in Figure 2a, an AFO applies forces to three different points of the limb (Edelstein & Bruckner, 2002). F_1 is applied to the proximal-posterior calf, F_2 to the foot sole and F_3 to the dorsal foot (Figure 2a). Three point pressure system will help manage the deformities such as excessive pronation and valgus angles. This system limits the motion around the joint axes and therefore rotations around the joint axes could be managed and joint stabilizations could be provided.

Stiffness, geometrical shape and material type are the main parameters which give to AFO its characteristic properties. AFO stiffness is an important parameter that directly has relation with other parameters taken into account AFO design, and should be determined properly to reduce the gait deficiencies (Esposito, Blanck, Harper, Hsu, & Wilken, 2014). AFO's stiffness depends on the type and level of deformity, and weight of patient; briefly the patients' biomechanical conditions. Different types of AFOs have different stiffness values. For example, a solid AFO should keep the ankle stable and inflexible. Therefore, they are designed thicker in the ankle section. AFO can have flexibility with a thinner thickness or a trimmed ankle section. Location of trimlines is determined according to goals such as holding ankle in fixed position, assisting dorsiflexion, allowing free dorsiflexion with free or restricted ankle plantar flexion. Also, trimline severity is an effective parameter on stiffness of AFO (Bielby et al., 2010). "How much section must be trimmed"

Figure 2. (a) Three-point force system, (b) trimlines for some design options

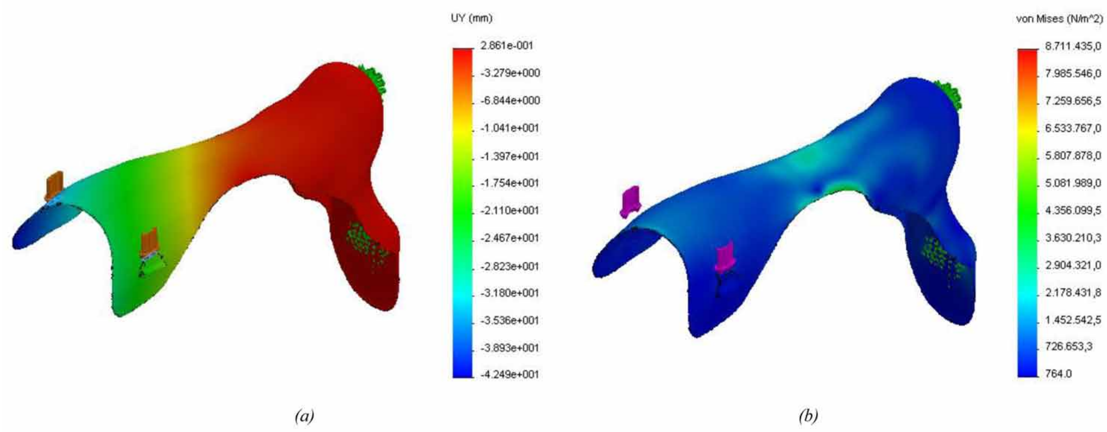


and "from where AFO is needed to be cut" should be determined in such a way to obtain an optimal stiffness. Therefore, geometrical shape of AFO is a key factor on determination of stiffness. Geometry and size of trimmed area and its location will affect allowed limits of the range of motion of ankle joint. Because, displacement distribution over AFO during stance phase of gait is directly related to the trimmed area in the AFO. In standard trim form, proximal trimline becomes 1,5-2 cm below the fibula head, ankle trimline must be 1 cm anterior to the tip of the malleoli and metatarsal trim-line must be just posterior to metatarsal heads. For a solid AFO design, an existing standard trimline is valid (Figure 2b). If a flexible AFO is intended to be designed, then ankle trimline and anterior trimline should be moved to behind the standard ankle trimline. To control the forefoot adduction metatarsal trimline, it should be moved forward covering metatarsal heads and toes (Figure 2b).

Also trimlines affect stress distribution over the AFO, when a force is applied to it (Figure 3). It is important to distribute the stress homogeneously over the AFO to not lead to plastic deformity. At this point, it would be beneficial to take advantage of a finite element software. Finite element method (FEM) has been used for designing more efficient AFOs (Ramsey, 2011). FEM is a numerical method to simulate the behavior of physical systems and presents time and cost effective solutions for various engineering problems. In FEM, a numerical model is constructed after the physical problem is translated into a mathematical model and then it is solved using a computer (Dhatt, Lefrançois, & Touzot, 2012). FEM enables to observe the effects of different trimlines on the stress/strain distribution over AFO models to test different AFO designs.

AFO models have free-form geometry. So it is difficult to draw a 3D AFO model with a CAD software. However, scanning technology provides having a complete 3D AFO model for analyzing in a finite element analysis (FEA) software. 3D scanning is commonly preferred for custom-made designs, prototyping, reverse engineering, industrial design, orthotic and prosthetic design, entertainment industry, inspection and digital archiving. 3D scanners basically convert the physical data of an object into digital data. The purpose of these systems is to construct a point cloud of the object. This data can be turned into 3D surface model of the scanned object and then it is possible to obtain 3D CAD model of the object. There are various systems for 3D scanning operation using different technologies such as laser, white light and x-ray scan. 3D optical scan is also one of the

Figure 3. (a) Displacement and (b) stress distribution of a trimmed AFO model



most popular scanning systems using for orthotic and prosthetic design works in biomechanics and dental areas (Balasundaram, Gurun, Neely, Ash-Rafzadeh, & Ravichandra, 2014; Kang, Kim, & Kim, 2016; Mikkelsen, Skorini, & Løgstrup Andersen, 2011). This scanning system consists of several steps (Figure 4). The object should be sprayed for obtaining matt surfaces before scanning. Different sizes of fringes are projected over the subject and then their photos are taken from different views by two high resolution digital cameras. The number of taken photos depends on size and complexity of the object. Later these photos are bought together and a point- cloud model is obtained. This model is converted into a 3D CAD model by determining surface number in the scan software. Surface number can be increased depending on the complexity of the object. At the final step, the model is verified by using deviation analysis according to a predetermined tolerance value.

Another design parameter is the material type which affects the stiffness level of the AFO. Material type is also related to other mechanical properties of AFOs. Properties, such as durability, fatigue strength, corrosion resistance and process ability depend on the material type. Moreover, material type is a determining factor in terms of the manufacturing cost of AFO. In AFO design, lightweight materials are desired and encouraged, especially when considering young patients. Polypropylene (Bregman et al., 2010), carbon fiber (King, Mnatsakanian, & Kissel, 2015), metal (Sherk, 2008) and leather are the materials used in AFO design.

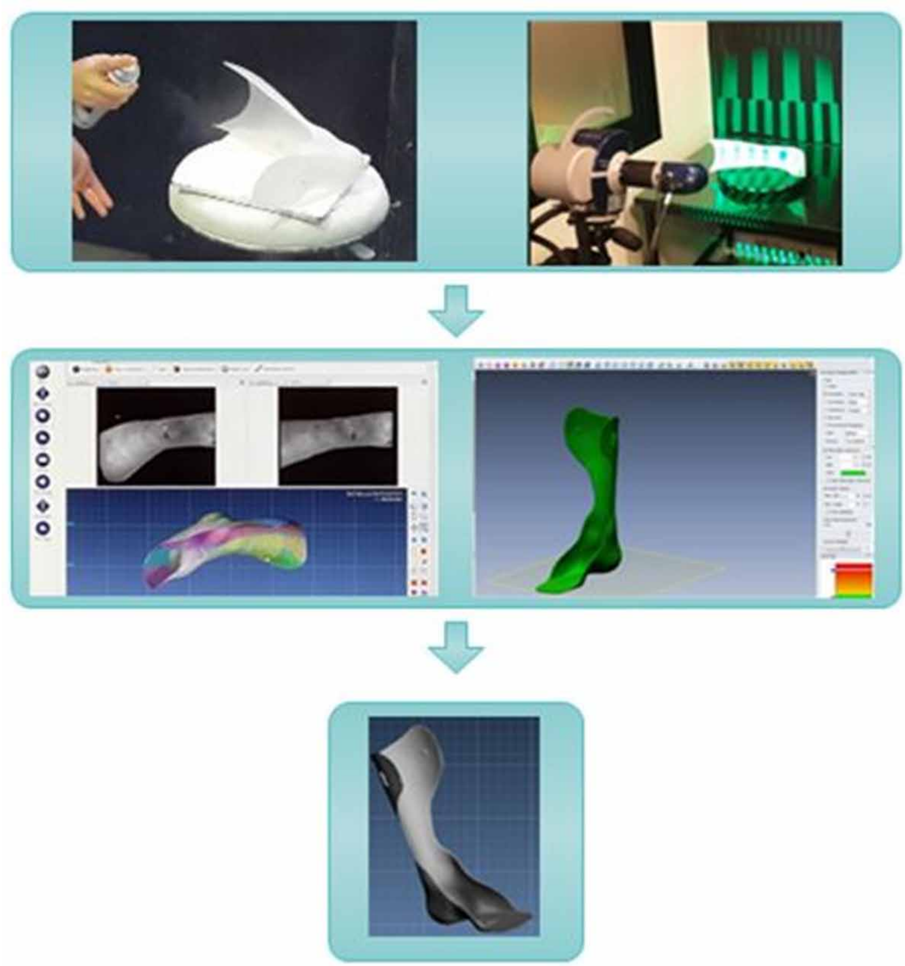
An optimum AFO design should be implemented according to the patient's specific conditions such as spastic movement, low-tone pronation, high-tone pronation or drop-foot and should provide the following properties.

An AFO should:

- Be ergonomically suitable to the patient's body,
- Minimize the skin and tissue injury as reducing or distributing the pressure around the limb,
- Prevent deformity, pain and contracture,
- Reduce consumption of energy during walking,
- Be light, durable and cosmetic,
- Be resistant against environmental effects,
- Be at reasonable cost and be produced in a proper time, and
- Be easy to use.

Hinged AFOs, which are of an important role among AFO designs, consist of a joint mechanism, and a calf and a foot component that are usually manufactured by molding technique (May & Lock-

Figure 4. Steps of 3D optical scanning



ard, 2011). The joint mechanisms that provide the control of plantarflexion or dorsiflexion are made of various materials such as metal, composite or plastic. There are also different types of joints for such functions as assisting, restricting or stopping. It is also possible to adjust the stiffness of AFO by means of some kinds of joint mechanisms (Kobayashi, Leung, Akazawa, & Hutchins, 2011). However, the stress distributes a wider area in the type of one-piece AFOs, while it is mainly concentrated around the joint in hinged type AFOs. Unless the design parameters are determined properly, then the joints, particularly metal ones, may be broken in short time. Many kinds of hinged AFO and joints have been designed for better solutions to improve the gait function efficiently so far (Carlson, 2004; Engelman, 2010; Kobayashi et al., 2011; Kramer & Hinshon, 2016; Schwartz, 2014; Wiggin, Sawicki, & Collins, 2012), and it is still a popular research area. On the other hand, there are some studies that investigate the effectiveness of hinged AFOs for different abnormal gait conditions (Kim, Eng, & Whittaker, 2004; Rha, Kim, & Park, 2010; Tyson & Thornton, 2001). For example, it is considered that if patients have a preexisting tendency to crouch, hinged AFO may not be a good solution (Hsu et al., 2008).

MANUFACTURE OF AFO

There are many material types used for AFO manufacture such as metal, plastic, synthetic fabrics or composites. However, because it is light, cosmetic and providing support and better contact with the body, plastics are commonly prescribed. Nevertheless, they have some disadvantages such as being non-adjustable. New designs have been proposed both to provide comfort to the patient and to improve the efficiency of available designs. New designs lead to development of new manufacturing methods. The most conventional manufacturing technique is the molding process in which the lower part of the leg is casted by producing a positive cast to represent patients' shank, ankle and foot. Moreover, different manufacturing methods have been improved due to the requirements of different design and material types (Morris, 2006).

Vacuum Molding Technique

In this technique (Figure 5), a thermoplastic sheet is heated to its softening temperature in an oven. The heating time depends on the oven temperature, material thickness, material type and oven efficiency. Then the heated thermoplastic sheet is forced against the contours of a mold by an orthotist. For the purpose of better formed orthosis, vacuum pressure is also applied to the material. The molds used in this process are called positive molds. Positive molds are produced from negative molds.

Negative Mold Production

The limb is isolated with the aid of a foil. Then a rope is placed in front of the limb in order to assist to cut and remove the negative mold. The limb is wrapped with a plaster bandage applying a little impression. The ankle is held at 90 degrees of flexion in a neutral position. Once the plaster mold has been hardened, it is cut over the rope with a cutting knife and removed from the limb. Then, the negative mold is put to the drying oven.

Positive Mold Production

The negative plaster mold is isolated and then a metal stick is placed into it. It is filled with liquid plaster and left to harden. Negative mold is removed from the positive mold. After cleaning process, positive mold is modified by scraping according to anthropometric measures of the patient, and finally mold is smoothed.

AFO Producing

A thermoplastic sheet of which thickness depends on material type, patient's weight, type and level of dysfunctions is heated in an oven. When the material has reached its softening temperature, it is wrapped around the positive mold by an orthotist. Pads and hinges should be placed to the related locations before the wrapping process. The thermoplastic sheet is pulled from their tips over the mold surface and edges of the sheet are combined by applying a moderate pressure. After the material cools, its redundant parts are cut by a scissors. Depending on prospectus there can be several design options. Once a design has been determined, trimline is marked on the orthosis and then the material is cut from the trimline. Then, locations of the straps are determined on the orthosis and they are placed. The goal of the straps is to keep the limb within orthosis in total contact. Therefore, straps should be placed at the correct angles and positions.

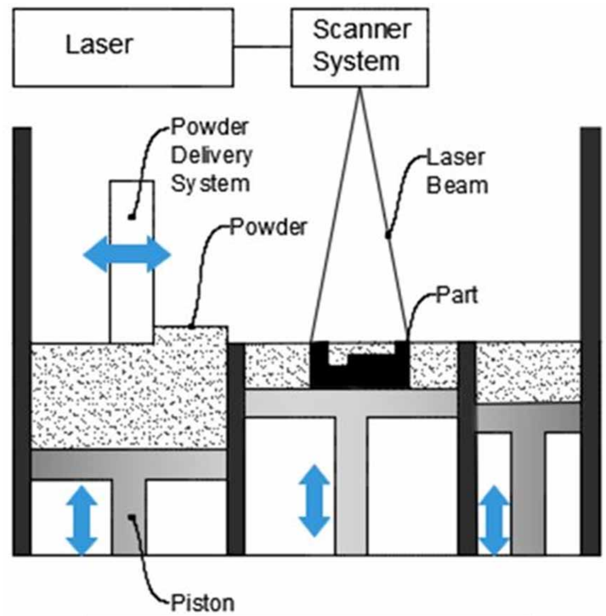
Carbon fiber AFOs are rather durable and light devices. They are manufactured in standard sizes for patients, but also it is possible to manufacture custom size carbon fiber AFO by using a positive mold of the patient's limb. Carbon fiber fabric layers are laid onto the modified positive mold with resin. The number and directions of layers should be arranged depending on the stiffness of the AFO.

Figure 5. Steps of vacuum molding technique: Limb is isolated with the aid of a foil and wrapped with a plaster bandage. Once the plaster mold has been hardened, it is removed from the limb and then the negative mold is obtained. The negative mold is isolated and filled with liquid plaster and left to harden. By doing so, positive mold is obtained. After cleaning process, positive mold is modified according to anthropometric measures of the patient. A thermoplastic sheet is heated in an oven. Then, it is wrapped around the positive mold. Pads and hinges are placed to the related locations before the wrapping process. The thermoplastic sheet is pulled from their tips over the mold surface and edges of the sheet are combined by applying a moderate pressure. After the material cools, its redundant parts are cut by a scissors. Trimline is marked on the orthosis and then the material is cut from the trimline. Then, the straps are placed on the orthesis

Additive Manufacturing (AM)

Additive manufacturing (AM), also known as 3D printing, is a rapid manufacturing technology that turn 3D CAD data into solid parts by using a number of additive processes, such as selective laser sintering (SLS), direct metal laser sintering (DMLS), selective laser melting (SLM), fused deposition modeling (FDM), stereolithography (SLA) and laminated object manufacturing (LOM). Additive manufacturing is of several advantages, such as enabling freeform design,

Figure 6. Selective laser sintering (SLS)



high dimensional accuracy, reducing raw material usage, and the time to market. However, there are also several disadvantages, such as low-volume production, limited materials, high build time and surface quality depending on layer thickness (Gao et al., 2015). AM is utilized in many fields such as automotive, aerospace and biomedical industries, and can be an economical solution for customized products and creating prototype of models.

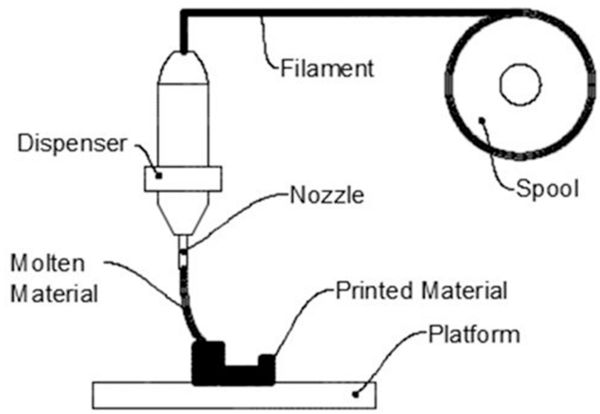
In additive manufacturing, the first step of the process is obtaining a 3D solid model. This can be accomplished by CAD software or 3D scanning systems. Then the model exported to 3D printer in stereolithography (STL) format (Ahn, Montero, Odell, Roundy, & Wright, 2002). Then the manufacturing process varying according to AM technique of the 3D printer machine is started.

SLS is one of the popular AM technique using laser (Figure 6). Parts are manufactured by sintering the powdered material. The material is heated and fused, after the laser has completed a scan process. By doing so, a layer is produced. After all layers has been produced and fused, model is completed.

There are a number of studies explore the feasibility of using SLS in AFO manufacturing. Faustini et al. (2008) evaluated the feasibility of an SLS-based manufacturing framework to produce patient-specific PD-AFOs. They reported that systematic and controlled design modifications can be possible in the AFO shape or volume which permits the exploration of the relative advantages of various passive dynamic PD-AFO designs. Another advantage is that additional design features such as holes and attachments can be easily integrated into an AFO design. Schrank (2011) reported that dimensional accuracy of the SLS process was within tolerances and material cost was acceptable. When the time saving parameter was considered, the SLS surpassed the traditional PD-AFO fabrication methods.

FDM, another popular AM process, uses production-grade thermoplastics (Figure 7). A plastic filament is wound in a coil on a spool. As material is extruded from a nozzle, the spool rotates and supplies filament to the extrusion nozzle. The material is heated in a dispenser and melted before extrusion. It hardens in a short time

Figure 7. Fused deposition modeling (FDM)



after the extrusion. The nozzle is moved along the horizontal and vertical directions by a numerically controlled mechanism (Bralla & Press, 2007; Miller, Vandome, & McBrewster, 2010). While the material is extruded as a thin ribbon on the work surface, the CAD model can be constructed layer by layer in a computer controlled pattern.

Number of AFO manufacturing researches using FDM process has been increasing day by day. In this technique, products can be manufactured within the repeatable dimensional accuracy. Patar et al. (2012) developed a DAFO prototype using FDM. The layer thickness was determined as 0.04 mm in their study. In the AFO model, ABS was used as FDM material and a DC motor provided dynamic feature of the AFO. They reported that the prototype model was much higher than the estimated cost. However, it is important to note that the cost of this model also includes a mechanism with DC motor.

Jin et al. (2015) evaluated additive manufacturing techniques of custom-made orthoses and prostheses in their review study. They concluded that AM technology enabled the fabrication of custom-made AFOs with proper fit and adequate strength, while it is not satisfied enough from the clinical, technological and economical point of views. Nevertheless, it is important to note that AM does not require molding process, which takes a considerable time, and an experienced orthoptist trimming the AFO.

There are also some researches on the process ability of materials for AM machines (Fiedler, Correa, Radusch, Wutzler, & Gerken, 2007). Additionally, some companies have been releasing new materials for AM machines. It seems that AM can be a good option for the AFO manufacturing with advancing of AM technology. The design concept for AM can be improved for more efficient products.

SELECTION OF AFOS

Developments in design and manufacture of orthoses affect the selection of the AFO. The proper selection of an AFO is crucial to support the patient during daily life activities. In this respect, biomechanical examination should be carefully implemented to ensure thorough assessment of gait functions and to gain feedback of patients' experiences properly. Generally orthoses are prescribed in order to improve patients activity of daily living (ADL) (World Health Organization, 2001). Therefore, it should be well analyzed that what the patients' gait abnormalities are, as well as the other ADL activities such as sitting, standing and even running. In order to understand the abnormalities of these different ADL activities, some functional tests or questioners should be applied to the patients or parents such as Functional Independence Measure for Children (Ziviani et al., 2002), Gross Motor Function Measurement (Russell et al., 2000), Client Satisfaction (Bravini et al., 2014), Functional Reach Test (Bravini et al., 2014). Additionally, some sophisticated laboratories including high speed cameras, force plates and electromyography sensors are used to objectively define the movement abnormalities during standing, sitting, stair ascending-descending, reaching, walking and running. After the definition of the dynamic problem of the activity, orthotic team, which is consisted of physiotherapist, doctor and orthotic technician, get to gather in order to decide the most appropriate orthotic design for the patient. After making the decision, it should be prescribed and manufactured in a short time. During the first try, the team should be with the patients and notes the fine tunings of the AFO for the best usage in ADL. The same functional tests should be re-performed after couple of weeks in order to define the functional changes that the AFO made in patient's life.

FUTURE RESEARCH DIRECTIONS

Orthotic designs focus on the improvement of the function and stability of patients during ADL. Therefore, different movement types require different supports or facilitations. Orthoses need to be lighter, more durable, more skin friendly and smarter. If smart designs and smart materials gather with better understanding of the patients' need, the orthotics may find an important role in their life. Also it is expected that with the improvement of the additive manufacturing techniques, more subject-specific AFOs would be fabricated, thereby leading to eliminate the most of the problems stemmed from the standard and common approaches on patients with different demands and diseases.

CONCLUSION

This chapter is intended to be useful for the orthotists, physiotherapists and engineers as well as the other health specialists who are eager to know about the usage of AFOs, their different designs, and different ways of their manufacture. Finally, we emphasized the importance of the evaluation of the patients and clearly understanding of their functional difficulties by using some well-known tests and questionnaires.

REFERENCES

Ahn, S.-H., Montero, M., Odell, D., Roundy, S., & Wright, P. K. (2002). Anisotropic material properties of fused deposition modeling ABS. *Rapid Prototyping Journal*, *8*(4), 248–257. doi:10.1108/13552540210441166

Balasundaram, A., Gurun, D., Neely, A., Ash-Rafzadeh, A., & Ravichandra, J. (2014). Novel CBCT and optical scanner-based implant treatment planning using a stereolithographic surgical guide: A multipronged diagnostic approach. *Implant Dentistry*, *23*(4), 401–406. doi:10.1097/ID.0000000000000128 PMID:25051414

Belda-Lois, J.-M., Barberà, R., Gómez, J., Baydal, J., Navarro, J., Gimeno, S., & Vera, P. (2006). Biomechanical requirements in upper-limb orthoses for tremor suppression. *Journal of Biomechanics*, *39*, S76. doi:10.1016/S0021-9290(06)83192-1

Bella, G. P., Rodrigues, N. B., Valenciano, P. J., Silva, L. M., & Souza, R. C. (2012). Correlation among the visual gait assessment scale, Edinburgh visual gait scale and observational gait scale in children with spastic diplegic cerebral palsy. *Brazilian Journal of Physical Therapy*, *16*(2), 134–140. doi:10.1590/S1413-35552012000200009 PMID:22584771

Bielby, S. A., Warrick, T. J., Benson, D., Brooks, R. E., Skewes, E., Alvarez, E., & DesJardins, J. D. (2010). Trimline severity significantly affects rotational stiffness of ankle-foot orthosis. *Journal of Prosthetics and Orthotics*, *22*(4), 204–210. doi:10.1097/JPO.0b013e3181f9082e

Bralla, J., & Press, I. (2007). *Handbook of Manufacturing Processes*. Industrial Press.

Bravini, E., Franchignoni, F., Ferriero, G., Giordano, A., Bakhsh, H., Sartorio, F., & Vercelli, S. (2014). Validation of the Italian version of the Client Satisfaction with Device module of the Orthotics and Prosthetics Users Survey. *Disability and Health Journal*, *7*(4), 442–447. doi:10.1016/j.dhjo.2014.04.002 PMID:25224984

Bregman, D. J., De Groot, V., Van Diggele, P., Meulman, H., Houdijk, H., & Harlaar, J. (2010). Polypropylene ankle foot orthoses to overcome drop-foot gait in central neurological patients: A mechanical and functional evaluation. *Prosthetics and Orthotics International*, *34*(3), 293–304. doi:10.3109/03093646.2010.495969 PMID:20738233

Carlson, J. M. (2004). *Adjustable mounting housing for orthotic ankle flexure joint*. Patent No: US 20040002672 A1.

Dalvand, H., Dehghan, L., Feizi, A., Hosseini, S. A., & Amirsalari, S. (2013). The impacts of hinged and solid ankle-foot orthoses on standing and walking in children with spastic diplegia. *Iranian Journal of Child Neurology*, *7*(4), 12–19. PMID:24665312

Dhatt, G., Lefrançois, E., & Touzot, G. (2012). *Finite element method*. John Wiley & Sons. doi:10.1002/9781118569764

Duffy, C. (1997). AFOs, energy consumption and gait in spina bifida. *Gait & Posture*, *6*(3), 278. doi:10.1016/S0966-6362(97)90089-8

Eddison, N., & Chockalingam, N. (2013). The effect of tuning ankle foot orthoses–footwear combination on the gait parameters of children with cerebral palsy. *Prosthetics and Orthotics International*, *37*(2), 95–107. doi:10.1177/0309364612450706 PMID:22833518

Edelstein, J. E., & Bruckner, J. (2002). *Orthotics: a comprehensive clinical approach*. Slack Thorofare.

Engelman, I. K. (2010). *Articulated orthosis providing lift support*. Patent No: US 7682322 B2.

Esposito, E. R., Blanck, R. V., Harper, N. G., Hsu, J. R., & Wilken, J. M. (2014). How does ankle-foot orthosis stiffness affect gait in patients with lower limb salvage? *Clinical Orthopaedics and Related Research*, *472*(10), 3026–3035. doi:10.1007/s11999-014-3661-3 PMID:24817379

Everaert, D. G., Stein, R. B., Abrams, G. M., Dromerick, A. W., Francisco, G. E., Hafner, B. J., & Kufta, C. V. (2013). Effect of a Foot-Drop Stimulator and Ankle–Foot Orthosis on Walking Performance After Stroke A Multicenter Randomized Controlled Trial. *Neurorehabilitation and Neural Repair*, *27*(7), 579–591. doi:10.1177/1545968313481278 PMID:23558080

Faustini, M. C., Neptune, R. R., Crawford, R. H., & Stanhope, S. J. (2008). Manufacture of passive dynamic ankle–foot orthoses using selective laser sintering. Biomedical Engineering. *IEEE Transactions on*, *55*(2), 784–790.

Fiedler, L., Correa, L. O. G., Radusch, H. J., Wutzler, A., & Gerken, J. (2007). Evaluation of Polypropylene Powder Grades in Consideration of the Laser Sintering Processability. *Journal of Plastic Technology, 3*(4).

Franceschini, M., Massucci, M., Ferrari, L., Agosti, M., Orsi, M., & Paroli, C. (2001). Gait with custom-made orthosis in hemiplegic patients: Preliminary data. *Gait & Posture*, *13*(2), 139–140.

Gao, W., Zhang, Y., Ramanujan, D., Ramani, K., Chen, Y., Williams, C. B., & Zavattieri, P. D. (2015). The status, challenges, and future of additive manufacturing in engineering. *Computer Aided Design*, *69*, 65–89. doi:10.1016/j.cad.2015.04.001

Guo, Y., Hao, Z., & Wan, C. (2016). Tribological characteristics of polyvinylpyrrolidone (PVP) as a lubrication additive for artificial knee joint. *Tribology International*, *93*, 214–219. doi:10.1016/j.triboint.2015.08.043

Heys, K. R., & Truscott, R. J. (2008). The stiffness of human cataract lenses is a function of both age and the type of cataract. *Experimental Eye Research*, *86*(4), 701–703. doi:10.1016/j.exer.2007.12.009 PMID:18289531

Hofmann, U. K., Thumm, S., Jordan, M., Walter, C., Rondak, I.-C., & Ipach, I. (2016). The Effects of Hip and Spine Orthoses on Braking Parameters: A Simulated Study With Healthy Subjects. *PM & R*, *8*(1), 35–44. doi:10.1016/j.pmrj.2015.06.002 PMID:26079866

Hsu, J. D., Michael, J., & Fisk, J. (2008). *AAOS atlas of orthoses and assistive devices*. Elsevier Health Sciences.

Jin, Y., Plott, J., Chen, R., Wensman, J., & Shih, A. (2015). Additive Manufacturing of Custom Orthoses and Prostheses–A Review. *Procedia CIRP*, *36*, 199–204. doi:10.1016/j.procir.2015.02.125

Kang, S.-H., Kim, Y.-H., & Kim, M.-K. (2016). Comparison of digital dental images yielded by digital dental casts, cone-beam computed tomography, and multislice computed tomography for measurement of dental area. *Oral Radiology*, 1–9.

Kim, C. M., Eng, J. J., & Whittaker, M. W. (2004). Effects of a simple functional electric system and/or a hinged ankle-foot orthosis on walking in persons with incomplete spinal cord injury. *Archives of Physical Medicine and Rehabilitation*, *85*(10), 1718–1723. doi:10.1016/j.apmr.2004.02.015 PMID:15468037

King, W., Mnatsakanian, A., & Kissel, J. (2015). "Toe Off" Style Carbon Fiber Ankle Foot Orthoses in Neuromuscular Disease: The OSUMC Experience (P7. 063). *Neurology, 84*(14S).

Kobayashi, T., Leung, A. K., Akazawa, Y., & Hutchins, S. W. (2011). Design of a stiffness-adjustable ankle-foot orthosis and its effect on ankle joint kinematics in patients with stroke. *Gait & Posture*, *33*(4), 721–723. doi:10.1016/j.gaitpost.2011.02.005 PMID:21376602

Kramer, T., & Hinshon, P. S. (2016). *Ankle Foot Orthotic Joint*. US Patent 20,160,030,223.

Lake, E., Ahmad, S., & Dobrashian, R. (2013). The sonographic appearances of breast implant rupture. *Clinical Radiology*, *68*(8), 851–858. doi:10.1016/j.crad.2013.03.014 PMID:23623260

Lam, W. K., Leong, J. C., Li, Y. H., Hu, Y., & Lu, W. W. (2005). Biomechanical and electromyographic evaluation of ankle foot orthosis and dynamic ankle foot orthosis in spastic cerebral palsy. *Gait & Posture*, *22*(3), 189–197. doi:10.1016/j.gaitpost.2004.09.011 PMID:16214658

Leardini, A., Aquila, A., Caravaggi, P., Ferraresi, C., & Giannini, S. (2014). Multi-segment foot mobility in a hinged ankle-foot orthosis: The effect of rotation axis position. *Gait & Posture*, *40*(1), 274–277. doi:10.1016/j.gaitpost.2014.03.188 PMID:24792637

Leone, D. J. (1987). A structural model for molded thermoplastic ankle-foot orthoses. *Journal of Biomechanical Engineering*, *109*(4), 305–310. doi:10.1115/1.3138685 PMID:3695430

May, B. J., & Lockard, M. A. (2011). *Prosthetics & orthotics in clinical practice: a case study approach*. FA Davis.

Mikkelsen, L. P., Skorini, R. Í., & Løgstrup Andersen, T. (2011). Biomechanical study of a drop foot brace. In *Proceedings of the 2011 SIMULIA Customer Conference*.

Miller, F. P., Vandome, A. F., & McBrewster, J. (2010). *Fused Deposition Modeling*. VDM Publishing.

Moisan, G., & Cantin, V. (2016). Effects of two types of foot orthoses on lower limb muscle activity before and after a one-month period of wear. *Gait & Posture*, *46*, 75–80. doi:10.1016/j.gaitpost.2016.02.014 PMID:27131181

Morris, C. (2007). Lower-limb orthoses. In C. Morris & L. Dias (Eds.), *Paediatric Orthotics: Orthotic management of children* (pp. 44–66). Chicago: Mac Keith Press.

Morris, C. (2007). Materials, Components and Fabrication. In C. Morris & L. Dias (Eds.), *Paediatric Orthotics: Orthotic management of children* (pp. 28–43). Chicago: Mac Keith Press.

Nolan, K. J., Savalia, K. K., Lequerica, A. H., & Elovic, E. P. (2009). Objective assessment of functional ambulation in adults with hemiplegia using ankle foot orthotics after stroke. *PM & R*, *1*(6), 524–529. doi:10.1016/j.pmrj.2009.04.011 PMID:19627941

Patar, A., Jamlus, N., Makhtar, K., Mahmud, J., & Komeda, T. (2012). Development of dynamic ankle foot orthosis for therapeutic application. *Procedia Engineering*, *41*, 1432–1440. doi:10.1016/j.proeng.2012.07.332

Radtka, S. A., Skinner, S. R., Dixon, D. M., & Johanson, M. E. (1997). A comparison of gait with solid, dynamic, and no ankle-foot orthoses in children with spastic cerebral palsy. *Physical Therapy*, *77*(4), 395–409. PMID:9105342

Radtka, S. A., Skinner, S. R., & Johanson, M. E. (2005). A comparison of gait with solid and hinged ankle-foot orthoses in children with spastic diplegic cerebral palsy. *Gait & Posture*, *21*(3), 303–310. doi:10.1016/j.gaitpost.2004.03.004 PMID:15760746

Ramsey, J. A. (2011). Development of a method for fabricating polypropylene non-articulated dorsiflexion assist ankle foot orthoses with predetermined stiffness. *Prosthetics and Orthotics International*, *35*(1), 54–69. doi:10.1177/0309364610394477 PMID:21515890

Rethlefsen, S., Kay, R., Dennis, S., Forstein, M., & Tolo, V. (1999). The effects of fixed and articulated ankle-foot orthoses on gait patterns in subjects with cerebral palsy. *Journal of Pediatric Orthopedics*, *19*(4), 470–474. doi:10.1097/01241398-199907000-00009 PMID:10412995

Rha, D. W., Kim, D. J., & Park, E. S. (2010). Effect of hinged ankle-foot orthoses on standing balance control in children with bilateral spastic cerebral palsy. *Yonsei Medical Journal*, *51*(5), 746–752. doi:10.3349/ymj.2010.51.5.746 PMID:20635451

Ridgewell, E., Rodda, J., Graham, H., & Sangeux, M. (2015). The effect of bilateral solid AFO on gait. *Gait & Posture*, *42*, S70–S71. doi:10.1016/j.gaitpost.2015.03.122

Ries, A., & Schwartz, M. (2015). Comparative effectiveness of ground reaction and solid ankle foot orthoses for crouch gait in children with cerebral palsy. *Gait & Posture*, *42*, S90. doi:10.1016/j.gaitpost.2015.06.164

Romkes, J., Hell, A., & Brunner, R. (2006). Changes in muscle activity in children with hemiplegic cerebral palsy while walking with and without ankle-foot orthoses. *Gait & Posture*, *24*(4), 467–474. doi:10.1016/j.gaitpost.2005.12.001 PMID:16413188

Russell, D. J., Avery, L. M., Rosenbaum, P. L., Raina, P. S., Walter, S. D., & Palisano, R. J. (2000). Improved scaling of the gross motor function measure for children with cerebral palsy: Evidence of reliability and validity. *Physical Therapy*, *80*(9), 873–885. PMID:10960935

Schrank, E. S., & Stanhope, S. J. (2011). Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework. *Journal of Rehabilitation Research and Development*, *48*(1), 31. doi:10.1682/JRRD.2009.12.0195 PMID:21328161

Schwartz, N. (2014). *Ankle-Foot Orthosis*. Patent No: US 8904674.

Sherief, A. E. A. A., Gazya, A. A. A., & El Gafaar, M. A. A. (2015). Integrated effect of treadmill training combined with dynamic ankle foot orthosis on balance in children with hemiplegic cerebral palsy. *The Egyptian Journal of Medical Human Genetics*, *16*(2), 173–179. doi:10.1016/j.ejmhg.2014.11.002

Sherk, K. A. (2008). Technical Note: The Development and Use of a Floating T-Strap on a Double Upright Metal AFO to Correct Coronal–Plane Pathologies and Reduce Skin Shear. *JPO: Journal of Prosthetics and Orthotics*, *20*(1), 24–26.

Tyson, S., & Thornton, H. (2001). The effect of a hinged ankle foot orthosis on hemiplegic gait: Objective measures and users opinions. *Clinical Rehabilitation*, *15*(1), 53–58. doi:10.1191/026921501673858908 PMID:11237162

Van Beeten, B., Hartman, A., & Houdijk, H. (2015). Optimizing knee kinematics in mid-stance by tuning the ankle foot orthoses-footwear combination of children with cerebral palsy: A case series. *Gait & Posture*, *42*, S88–S89. doi:10.1016/j.gaitpost.2015.06.162

Van Gestel, L., Molenaers, G., Huenaerts, C., Seyler, J., & Desloovere, K. (2008). Effect of dynamic orthoses on gait: A retrospective control study in children with hemiplegia. *Developmental Medicine and Child Neurology*, *50*(1), 63–67. doi:10.1111/j.1469-8749.2007.02014.x PMID:18173633

White, H., Jenkins, J., Neace, W. P., Tylkowski, C., & Walker, J. (2002). Clinically prescribed orthoses demonstrate an increase in velocity of gait in children with cerebral palsy: A retrospective study. *Developmental Medicine and Child Neurology*, *44*(4), 227–232. doi:10.1017/S0012162201001992 PMID:11995890

Wiggin, M. B., Sawicki, G. S., & Collins, S. H. (2013). *Apparatus and clutch for using controlled storage and release of mechanical energy to aid locomotion*. Patent No: US20130046218 A1.

World Health Organization. (2001). *International classification of functioning, disability and health: ICF*. World Health Organization.

Ziviani, J., Ottenbacher, K. J., Shephard, K., Foreman, S., Astbury, W., & Ireland, P. (2002). Concurrent validity of the Functional Independence Measure for Children and the Pediatric Evaluation of Disabilities Inventory in children with developmental disabilities and acquired brain injuries. *Physical & Occupational Therapy in Pediatrics*, *21*(2-3), 91–101. doi:10.1080/J006v21n02_08 PMID:12029858

ADDITIONAL READING

Kobayashi, T., Leung, A. K. L., & Hutchins, S. W. (2011). Techniques to measure rigidity of ankle-foot orthosis: A review. *Journal of Rehabilitation Research and Development*, *48*(5), 565–576. doi:10.1682/JRRD.2010.10.0193 PMID:21674406

Tyson, S. F., Sadeghi-Demneh, E., & Nester, C. J. (2013). A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. *Clinical Rehabilitation*, *27*(10), 879–891. doi:10.1177/0269215513486497 PMID:23798747

KEY TERMS AND DEFINITIONS

AFO: Ankle-foot-orthosis is an assistive device designed to improve abnormal lower limb motor functions.

AM: Additive manufacturing is the rapid manufacturing technology that converts 3D CAD data to physical model by such methods as selective laser sintering, direct metal laser sintering, selective laser melting, fused deposition modeling, stereolithography, laminated object manufacturing and etc.

Gait: A manner of walking that shows the sequence of foot movements and also other parts of the body.

Orthosis: Externally applied bio-mechanical device to the body parts to control their motions and also provides protection and support.

Stiffness: An important AFO design parameter that is the resistance of the AFO to deformation by an applied force.

Trimline: Border of the trimmed section of the orthosis that is an important parameter in determining of AFO stiffness.

Vacuum Molding: A common AFO manufacturing technique in that heated sheet of plastic is laid over a positive lower limb mold and formed by the help of vacuum.